SEP 6 2002

510(k) Summary

Submitter's Name/Address
Abbott Laboratories
1920 Hurd Drive
Irving, TX 75038

Contact Person
Michele Smith-Waheed
Senior Regulatory Specialist MS 1-8
Regulatory Affairs
(972) 518-7466
Fax (972) 753-3367

Date of Preparation of this Summary:	June 28, 2002
Device Trade or Proprietary Name:	Direct Bilirubin
Device Common/Usual Name or Classification Name:	Direct Bilirubin
Classification Number/Class:	CIG, Class II

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K022180

Test Description:

Direct Bilirubin is an in vitro diagnostic assay for the quantitative determination of direct bilirubin in human serum and plasma. Direct (conjugated) bilirubin couples with a diazonium salt in the presence of sulfamic acid to form the colored compound, azobilirubin. The increase in absorbance at 548 nm due to azobilirubin formation is proportional to the direct bilirubin concentration.

Substantial Equivalence:

The Direct Bilirubin assay is substantially equivalent to the Roche Direct Bilirubin assay on the Hitachi® 717 Analyzer.

Both assays yield similar Performance Characteristics.

Similarities:

- Both assays are in vitro colorimetric assays.
- Both assays can be used for the quantitative determination of direct bilirubin.
- Both assays yield similar clinical results.
- Both assays are based on the reaction of bilirubin with a diazonium salt in the presence of acid.

Differences:

- Human serum and plasma are suitable specimens for the Direct Bilirubin assay and only human serum is a suitable specimen for Roche Direct Bilirubin assay.
- There is a difference between the assay ranges.
- There is a difference in the use of calibrators.

Intended Use:

The Direct Bilirubin assay is used for the quantitation of direct bilirubin in human serum and plasma.

Performance Characteristics:

Comparative performance studies were conducted using the AEROSET® System and ARCHITECT® c8000™ System. The Direct Bilirubin assay method comparison yielded acceptable correlation with the Roche Direct Bilirubin assay on the Hitachi 717 Analyzer. On the AEROSET System, the correlation coefficient = 0.995, slope = 1.08, and the Y-intercept = 0.21 mg/dL. On the ARCHITECT c8000 System, the correlation coefficient = 0.996, slope = 1.08, and the Y-intercept = 0.21 mg/dL. Precision studies were conducted using the Direct Bilirubin assay. Within-run, between-run, and between-day studies were performed using four levels of control material. On the AEROSET System, the total %CV for Level 1 ranged from 3.6 to 4.1%, Level 2 ranged from 0.9 to 2.6%, Level 3 ranged from 1.0 to 2.7%, and Level 4 ranged from 0.7 to 2.6 %. On the ARCHITECT c8000 System, the total %CV for Level 1 ranged from 3.0 to 3.6%, Level 2 ranged from 0.9 to 1.2%, Level 3 ranged from 1.3 to 1.5%, and Level 4 ranged from 0.8 to 1.1 %. The Direct Bilirubin assay range is 0.1 to 16.9 mg/dL. The limit of quantitation (sensitivity) of the Direct Bilirubin assay is 0.04 mg/dL on the AEROSET System and 0.04 mg/dL on the ARCHITECT c8000 System. These data demonstrate that the performance of the Direct Bilirubin assay is substantially equivalent to the performance of the Roche Direct Bilirubin assay on the Hitachi 717 Analyzer.

Conclusion:

The Direct Bilirubin assay is substantially equivalent to the Roche Direct Bilirubin assay on the Hitachi 717 Analyzer as demonstrated by results obtained in the studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 6 2002

Ms. Michele Smith-Waheed
Senior Regulatory Specialist
Abbott Laboratories
1920 Hurd Drive
Irving, TX 75038

Re: k022180
Trade/Device Name: Direct bilirubin
Regulation Number: 21 CFR 862.1110
Regulation Name: Bilirubin (total and direct) Test System
Regulatory Class: Class II
Product Code: CIG, JIT
Dated: June 28, 2002
Received: July 3, 2002

Dear Ms. Smith-Waheed:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022180

Device Name: Direct Bilirubin

Indications For Use:

The Direct Bilirubin assay is used for the quantitation of direct bilirubin in human serum and plasma. Measurement of direct bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, is used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Veronica J Calhoun for Dr Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022180